

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

B4



Europäisches Patentamt
European Patent Office
Office européen des brevets



⑪ Publication number:

0 437 063 A2

443

F

⑫

EUROPEAN PATENT APPLICATION

⑬ Application number: 90313758.6

⑮ Int. Cl. 5: A61B 17/04

⑭ Date of filing: 17.12.90

⑯ Priority: 12.01.90 US 464347

⑰ Date of publication of application:
17.07.91 Bulletin 91/29

⑱ Designated Contracting States:
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

⑲ Applicant: VANCE PRODUCTS
INCORPORATED d/b/a COOK UROLOGICAL
INCORPORATED and COOK OB/GYN
1100 West Morgan Street
Spencer Indiana 47460(US)

⑳ Inventor: Foster, Thomas Lee
R.R. No. 1, Box 755
Poland, Indiana 47868(US)

㉑ Representative: Johnston, Kenneth Graham
5 Mornington Road
Woodford Green Essex, IG8 OTU(GB)

㉒ Instrument for securing a suture needle.

㉓ A needle driver instrument suitable for use with a trocar sheath in operative endoscopic surgical procedures such as laparoscopic and pelviscopic procedures is disclosed for driving a curved suture needle. The needle driver instrument comprises an elongated cylindrical tube member having a channel formed about the distal end thereof for receiving either a curved or a straight suture needle. The channel is transversely formed through the elongated member and has a plurality of surfaces to orient and fix the suture needle in a predetermined orientation. A wedge operable across the channel and through the passageway of the elongated member wedges the needle between at least two of the contact surfaces of the channel to fixedly position the suture needle in the desired orientation. At the proximal end of the device is a handle with a generally U-shaped spring extending therefrom for manual operation of the wedge. A rod extending from the wedge through the elongated member of the instrument is connected to the spring for actuation and operation of the wedge. The device is comprised of component parts which are easily disassembled for cleaning and sterilization.

EP 0 437 063 A2

INSTRUMENT FOR SECURING A SUTURE NEEDLE

This invention relates to instruments for holding suture needles.

U.S. Patent 2,363,334 describes a known form of surgical needle holder.

In limited access endoscopic procedures, surgical instruments of limited size are required to be inserted through a trocar sheath, and it is extremely important that the needles, and particularly curved needles, be held efficiently. It is highly desirable that curved needles be constantly maintained in perfect alignment along their own curvature during suturing.

Known needle holders tend to be too bulky for use in restricted surgical site areas and unsuitable for insertion through a trocar sheath.

According to the present invention there is provided an instrument as defined in claim 1.

In an embodiment in which the end part of the elongated arrangement comprises a single or coplanar beveled surface, and the opening is a channel, then the beveled surface preferably is inclined at other than 90° to the axis to point away from, and force the needle away from the lateral opening of the channel.

In another embodiment in which the end part of the elongated arrangement comprises an effective plurality of beveled surfaces, such as V-shaped or concave surfaces, the latter conform to the shape of the needle and urge the needle to be clamped in a non-rotatable manner.

The opening of the tubular member is transverse or lateral to the axis of the member, namely at 90° or any other smaller angle which permits suitable siting of the needle.

In the embodiments, the contour of the opening and the shape of the beveled surface(s) conform to the outer contour of the needle and effectively clamp the needle in a non-rotatable manner. If the elongated arrangement is tubular, the beveled surface(s) is formed by the surface of the rim of the tube.

The configuration of angles between the beveled surface and two surfaces of the channel at 60° (first and second surfaces) has been found to orient a curved suture needle in the same orientation with respect to the elongated member. The contact surfaces formed in the elongated member and the engaging wedge segment form at least four and as many as six or more contact surfaces with a tubular engaging segment for fixedly positioning a curved suture needle in the same orientation each time the suture needle is grasped.

Curved suture needles typically have an elliptically shaped cross sectional area with a series of grooves longitudinally formed in the surface of the

needle. The generally cross-sectional elliptical shape of curved needles and the ridges longitudinally formed on the surface of the needle further facilitate the almost identical positioning of a curved suture needle when inserted and wedged in the channel of the present medical instrument. The ease of movement of the wedge across the channel during an endoscopic surgical procedure significantly decreases the time required by the surgeon for suturing.

Brief description of the drawings

FIG.1 depicts an embodiment instrument for holding suture needles;

15 FIG.2 depicts a cross-sectional side view of part of the instrument of FIG.1;

FIG.3 depicts a partial cross-sectional side view of another part of the instrument of FIG.1;

20 FIG.4 depicts a top view of part of the instrument of FIG.1; and

FIG.5 depicts a top view of part of an alternative embodiment instrument.

The instrument of FIG.1 includes an elongated member 101, such as a cylindrical tube, which is passed through the passageway of trocar sheath 102 and into the peritoneal cavity 103 of patient 104. The trocar sheath is inserted into the patient for performing a minimally invasive endoscopic surgical procedure such as an operative laparoscopic or pelviscopic procedure. The distal end of the elongated member includes a channel 105 for receiving curved suture needle 106, which is inserted into the peritoneal cavity with the elongated member or alternatively via another trocar sheath 107. Suture thread is connected to one end of the curved needle for suturing tissue together or closing the end of a tube severed in surgery. Attached at the proximal end of elongated member tube 101 is handle 108 with a generally U-shaped spring 109 extending therefrom for manual operation by the surgeon. This spring is easily grasped between the thumb and fingers of the surgeon for operating a wedge 110 which operates across the channel for grasping and fixedly positioning the suture needle.

50 Depicted in FIG.2 is a partial cross-sectional side view of distal end 201 of elongated member 101 of the needle driver instrument. Elongated member 101 comprises a 7-gauge stainless steel tube approximately 30.5cms (12") in length for insertion through a 5mm trocar sheath. The outside diameter of a 7-gauge stainless steel regular wall tube is approximately 0.46cms (0.180") with an inside diameter of 0.38cms (0.150"). A cylindrically shaped hollow passageway 202 extends the entire

length of the tube along longitudinal axis 203. Channel 105 is transversely cut in tube 101 and through passageway 202. As shown, the channel is cut such that four surfaces 204-207 are formed in the semi-cylindrical wall. A first contact surface 205 is substantially parallel to longitudinal axis 203 at a depth of 0.29cms (0.115") from the opening of the channel or the outer surface of tube 101. Second contact surface 204 forms an approximately 60° angle with longitudinal axis 203 with one end of the surface at the opening of the channel approximately 0.584cms (0.230") from the extreme distal end 208 of the tube. First contact surface 205 is approximately 0.13cms (0.050") in length.

The third contact surface 206 of the channel is approximately 0.495cms (0.195") in length and rises to a height of approximately 0.025cms (0.010") from the opening of channel 105.

The fourth contact surface 207 of the channel rises at approximately a 45° angle with respect to the longitudinal axis to the outside surface of the elongated tube. The third and fourth contact surfaces 206 and 207 guide the curved suture needle 106 into position and/or contact with first and second contact surfaces 205 and 204 as shown. Suture needle 106 at a point approximately mid-point through its curvature exhibits an elliptically-shaped cross section 209 with a plurality of grooves 210 and 211 formed on the outer and inner arc surfaces of the needle, respectively.

Wedge 110 comprises elongated segment 214 and an engaging segment 212 with beveled surface 213. The engaging segment, such as a cylindrical rod or tube, is silver soldered to elongated segment 214, such as a cylindrical rod or linkage tube, which extends through passageway 202 of elongated tubular member 101 into the passageway of handle 108. Engaging segment 212 is approximately 1.27cms (0.50") in length and is comprised of 9-gauge regular wall tubing having an outside dimension of 0.376cms (0.148") with an inside diameter of 0.3cms (0.118"). Beveled surface 213 forms an angle of approximately 14° with respect to the longitudinal axis of the elongated member. The use of a tube for engaging segment 212 provide two separate contact areas for engaging curved suture needle 106.

A second beveled surface 215 at approximately a 45° angle is formed at the distal end of the engaging segment to reduce the sharpness of the distal end of the engaging segment so as not to extend beyond the distal end of outer elongated tubular member 101 while in use. A circular radius 216 is formed at the very distal end of the engaging segment to prevent any possible injury or extension of the engaging segment from passageway 202.

Elongated segment 214 is a stainless steel rod

approximately 32.07cms (12.625") in length with an outside diameter of 0.317 cms (0.125").

When wedge 212 is operated toward the distal end of passageway 202 with curved suture needle 106 in channel 105, the outer surface of the suture needle makes contact and is wedged against channel contact surfaces 204 and 205 and beveled surface 213 of the wedge. A longitudinal force applied to the proximal end of the cylindrical rod forces the wedge toward the distal end of elongated member 101 wedging the suture needle in an approximate 90° orientation with respect to longitudinal axis 203 as shown. The angles, as specified, have been experimentally found to hold the suture needle with the greatest amount of force in the indicated, approximate right-angle orientation with respect to the elongated member. This orientation is preferred by surgeons performing operative laparoscopic procedures to enable them to form uniform sutures through the trocar sheath. However, the contact surface and beveled surface angles may be formed to provide the suture needle with any other side view angular orientation with respect to longitudinal axis 203.

Depicted in FIG.4 is a top view of the distal end of elongated member 101 with curved suture needle 106 wedged in channel 105. Engaging segment 212 of the wedge forces curved suture needle 106 into contact with contact surfaces 204 and 205 of channel 105 and beveled surface 213 of the wedge. When wedged into channel 105, needle 106 forms an angle 401 such as approximately 90° with respect to longitudinal axis 203 as viewed from the top. Angle 401 forms but just one orientation that has been experimentally found to be preferred by surgeons performing endoscopic surgical procedures.

Depicted in FIG.5 is a top view of the distal end of elongated member 101 with curved suture needle 106 in an alternative embodiment channel 501. When wedged into alternative embodiment channel 501, needle forms an angle 502 such as approximately 45° with respect to longitudinal axis 203 as viewed from the top. Channel surfaces 503-506 are formed in elongated member 101 and beveled surface 507 of engaging segment 508 in the same manner as depicted in FIG.4, except the channel and beveled surface are cut at a 45° rather than a 90° orientation. This 90°, or 45° or less orientation of the channel is to be regarded as being laterally positioned, causes the pointed end of the suture needle to extend beyond distal end 509 of the elongated member for extremely limited space applications or when the surgeon simply wants the needle point to extend beyond distal end 509 for suturing. Any top view angular orientation is contemplated. However, this 45° angular orientation is preferred. Other combinations of top view

and side view angular orientations are also contemplated depending on the preference of the surgeon.

Depicted in FIG.3 is the proximal end of the instrument with handle 108 and generally U-shaped spring 109. The handle comprises a second elongated tubular member 301 having a passageway 302 positioned about longitudinal axis 203 extending from the first elongated tubular member 101. The second tubular member comprises a series 6061 T-6 drawn aluminum tube, rough tumbled and anodized blue in colour having a 1.27cms (0.500") outside diameter and an inside diameter of 0.94cms (0.370"). The tube is approximately 8.26cms (3.250") in length with a plurality of threads 303 and 304 formed in the inside surface of the tube. The distal threads 303 are approximately 0.95cms (0.375") in length, whereas proximal threads 304 extend approximately 1.27cms (0.500") into the proximal end of the tube. An elongated slot 305 is longitudinally formed in the wall of tube 301 approximately 2.54cms (1") in length and 0.476cms (0.1875") in width at a distance of 0.95cms (0.375") from the distal end 306 of the second elongated tubular member. The proximal end 307 of cylindrical rod 214 is inserted into a larger diameter cylindrical tube 308 and soldered therein using silver solder 309. Cylindrical tube 308 is a series 300 stainless steel tube approximately 3.8cms (1.5") in length with an outside diameter of 0.91cms (0.360") and an inside diameter of 0.325cms (0.128"). Centered at approximately 1.9cms (0.750") from the distal end thereof is a 0.476cms (3/16") radial hole 327 extending to passageway 310 of the tube. The L-shaped distal end 311 of spring 109 is inserted through slot 305 of the handle tube and into the radial hole 327 of tube 308 for moving the wedge including rod segment 214 within the passageways of the handle and elongated members.

At the distal end of elongated cylindrical tube 301 is front cap 312 which screws into the passageway of tube handle 108. The proximal end of tube 101 is silver soldered to front cap 312. Front cap 312 is approximately 0.76cms (0.300") in length and is formed from type 301 stainless steel rod. The outside diameter of the cap is 1.59cms (0.625") with a 0.46cms (0.182") inside diameter passageway therethrough. A plurality of threads 314 such as 7/16-20 threads with a maximum outside dimension of 1.09cms (0.430") are formed therein.

End cap 313 is formed from a 1.27cms (0.500") diameter stainless steel rod. The rod is approximately 1.9cms (0.75") in length with a threaded portion of, for example, 7/16-20 threads formed at the distal end thereof. The threads are approximately 0.48cms (3/16") in length. A recess

318 of approximately 0.48cms (3/16") in length with a 0.762cms (0.300") diameter relief is formed therein to receive the proximal end 316 of the generally U-shaped spring which is formed into an

5 eye around the relief area of the end cap. An internal passageway 319 of approximately 0.317cms (0.125") is drilled and counter sunk through the longitudinal axis of the rod. A knurled portion 320 of 0.81cms (0.32") is formed on the proximal end cap for turning the cap into the handle tube 108.

The generally U-shaped spring 109 of the handle is covered with a tubular plastic material 315 to facilitate easy handling of the spring. The surgical instrument is easily disassembled for cleaning and subsequent reuse due to the modular construction thereof. A similar medical instrument may be formed with 12-gauge tubing for the elongated member to facilitate use through a 3mm trocar. In such instance, the channel formed at the distal end of the tube would start approximately 0.254cms (0.100") from the distal end with a maximum depth of 0.165cms (0.065") extending up to 0.135cms (0.053") for the start of the fourth contact surface. 20 Parallel contact surface 210 would be approximately 0.127cms (0.050") in length with third contact surface 208 being 0.127cms (0.05") in length. These dimensions would facilitate the preferred angles for securing a smaller curved suture needle.

25 30 The suture needle can be curved or straight. It is also contemplated that a coil compression spring be inserted in the tubular handle to force the wedge against a suture needle inserted in the channel. The coil spring would be compressed and released by manually activated lever assemblies.

Claims

1. An instrument for holding a suture needle (106), the instrument comprising a tubular member (101) with a transverse opening (105) therein proximate the distal end thereof, the opening serving to receive the needle, and an elongated arrangement (212,214) movable within and along the longitudinal axis of the tubular member and operable to exert a force on the needle and to thereby secure the latter in the opening, characterised in that the end of the elongated arrangement has a beveled surface inclined to said longitudinal axis and serving to exert a force on the needle in a direction inclined to the axis, thereby clamping the needle.
2. An instrument according to claim 1, characterised in that the opening is a channel (105) with an entrance thereto for laterally receiving the needle, and in that the beveled surface is

inclined so that the said force is exerted in a direction away from the said entrance.

3. An instrument according to claim 2, characterised in that the interior of the channel is shaped to conform to the contour of part of the said needle, to minimize rotation of the needle. 5

4. An instrument according to claim 3, characterised in that the said beveled surface is adapted to conform to the contour of another part of the said needle to further minimize the said rotation, and increase the clamping. 10

5. An instrument according to claim 4, characterised in that the beveled surface is formed of a plurality of parts conforming to the contour(s) of the said other part of the needle. 15

6. An instrument according to any one of claims 2 to 5, characterised in that the elongated arrangement is spring urged toward the channel, and is solid and/or tubular, and in that when the arrangement is tubular, the beveled surface is formed by the edge of a tube. 20

7. An instrument according to any one of claims 2 to 6, characterised in that the channel has a first contact surface (205) substantially parallel to the longitudinal axis, and a second surface (204) at an acute angle with respect to the first surface, so as to form two clamping surfaces for the needle, a third clamping surface being provided by the said beveled surface. 25

8. An instrument according to any one preceding claim, further characterised by a handle (108) attached to the proximal end of the instrument, and with a control member (109) for releasing and engaging the elongated arrangement. 30

9. An instrument according to claim 8, characterised in that the control member is spring loaded (109) to urge the elongated arrangement along the tubular member and a handle passage into the clamped condition. 35

10. An instrument according to claim 9, characterised in that the elongated arrangement includes a segment (214) movable within the tubular member and the passageway (101,312) of the handle. 40

11. An instrument according to claim 9 or 10, characterised in that the control member is in the form of a hand operated spring with one end connected to the proximal end of the instrument and the other end movable to move 45

the elongated segment. 50

12. A medical instrument for driving a suture needle through tissue, comprising: an elongated member having a longitudinal passageway therein; a channel capable of receiving said needle and positioned in said elongated member about a distal end thereof and transverse through said passageway; and a wedge positioned within said passageway and operable across said channel to secure said needle between said elongated member and said wedge when said needle is positioned in said channel. 55

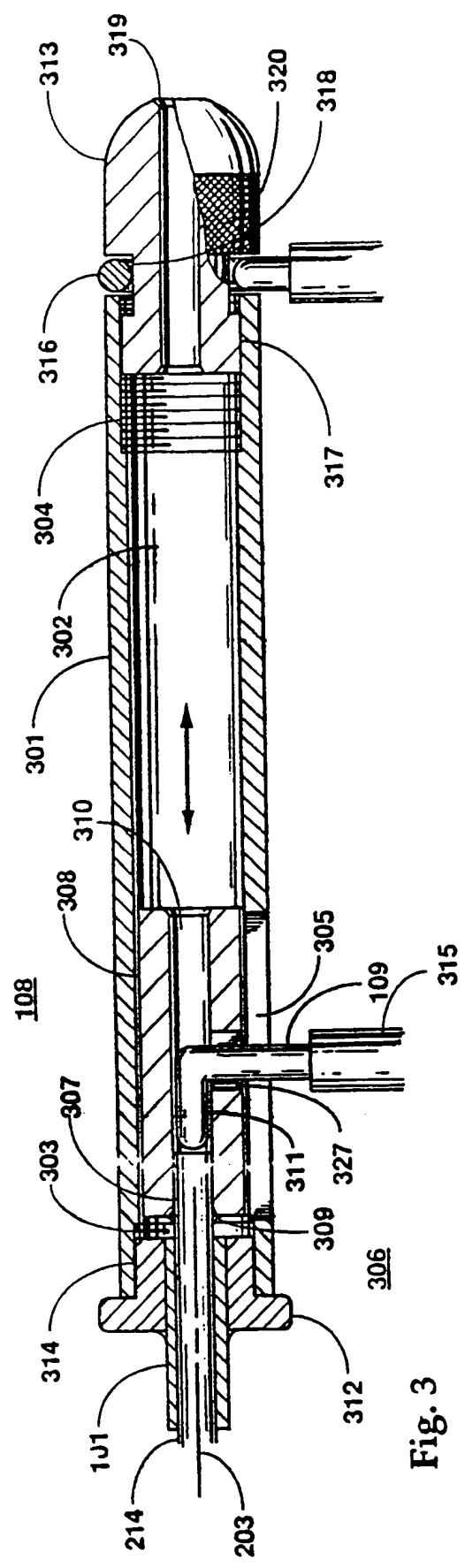


Fig. 3

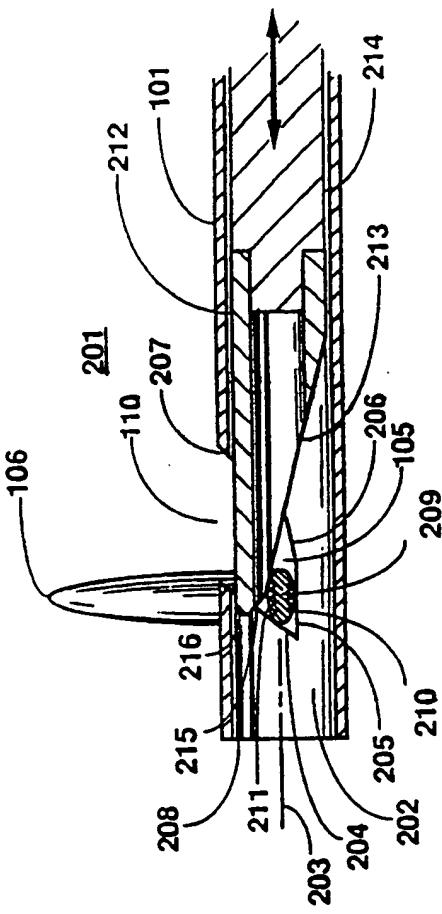


Fig. 2

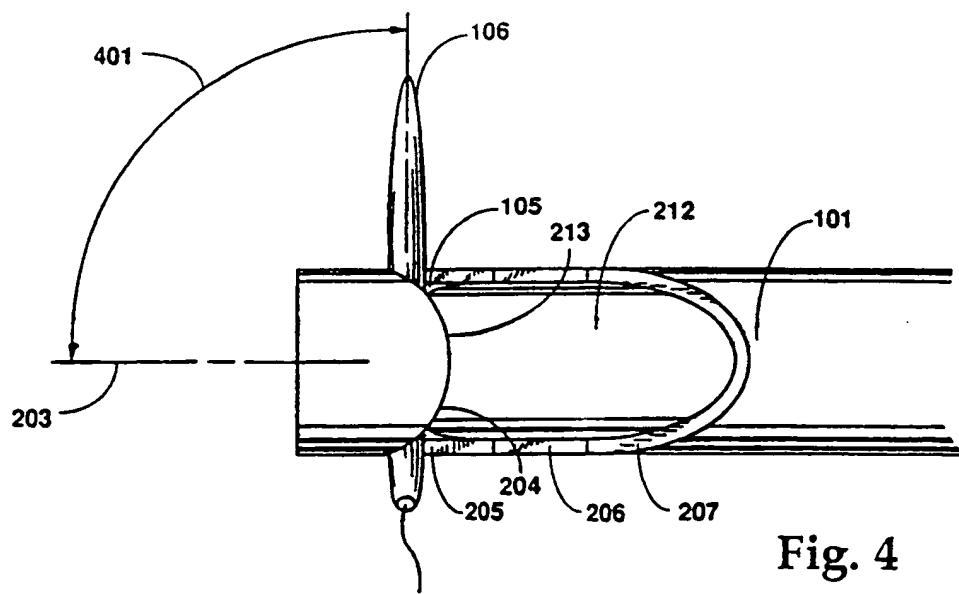


Fig. 4

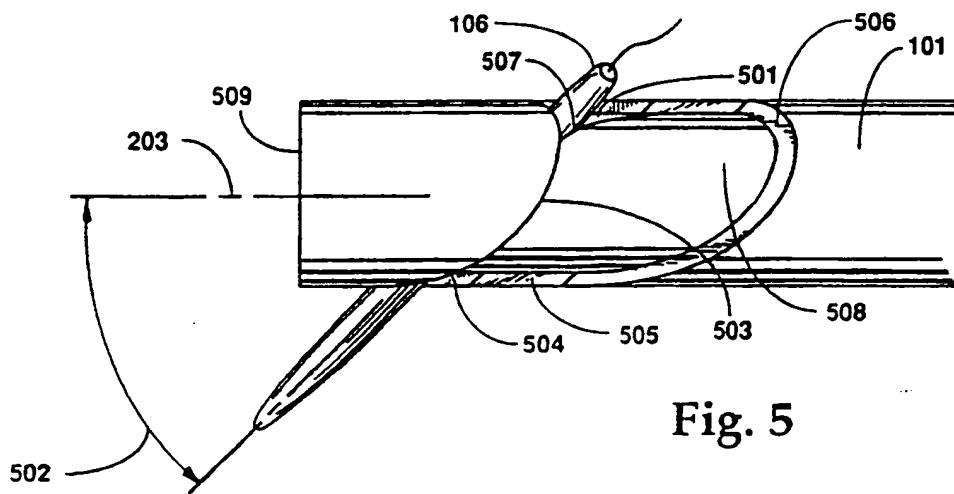


Fig. 5

